K011116 (1)

APR 2 4 2001

510(k) SUMMARY
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DATE:	January 31, 2001
CONTACT PERSON:	Linda K. Dillon Chuck Lakel
TRADE NAME OF DEVICE:	Pasco MIC and MIC/ID Panels
COMMON NAME:	ESBL Confirmatory Test
CLASSIFICATION NAME:	Class II Antimicrobial Susceptibility Test Microbiology Panel #83

SUBSTANTIAL EQUIVALENCE:
In review of previous 510(k) notifications for the Pasco MIC and MIC/ID panels (most recently: K001953, August 10, 2000 RE: Amoxicillin; K001887, August 9, 2000 RE: Ampicillin; K001721, August 4, 2000 RE: Clarithromycin; K001612, July 18, 2000 RE: Linezolid; K001516, July 12, 2000 RE: Moxifloxacin; K992853, November 4, 1999 RE: Cefdinir; K992726, November 3, 1999 RE: Synercid (non-fastidious); K992717, November 2, 1999 RE: Synercid; K992646, October 19, 1999 RE: Penicillin; K992647, October 19, 1999 RE: Erythromycin; K992593, October 14, 1999 RE: Chloramphenicol; K992562, October 13, 1999 RE: Ceftriaxone; K992568, October 14, 1999 RE: Cefotaxime; K992507, October 18, 1999 RE: Trovafloxacin; K992546, October 12, 1999 RE: Meropenem; K992420, September 27, 1999 RE: Sparfloxacin; K992296, September 21, 1999 RE: Vancomycin; K992297, September 3, 1999 RE: Levofloxacin; K992143, September 16, 1999 RE: Clindamycin; K992108, September 3, 1999 RE: Cefepime; K992076, August 30, 1999 RE: Cefuroxime; K992059, August 30, 1999 RE: Imipenem; K992077, September 3, 1999 RE: Ofloxacin; K991925, August 20, 1999 RE: Amoxicillin/Clavulanic Acid; and K946126, January 17, 1995 RE: Detection of resistant pneumococci), the FDA has determined the Pasco panels to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DESCRIPTION OF THE DEVICE:
Varying concentrations of antimicrobial agents (usually in two-fold dilutions) are dispensed into the Pasco panels and the panels are then frozen. Panels are thawed prior to use, inoculated with the test organisms, incubated the traditional 16-24 hours and panels are then observed for visible growth or color changes as described in the package insert.

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The lowest concentration of each antimicrobial agent with no apparent visible growth of the test organism is recorded as the minimum inhibitory concentration (MIC). Changes in pH and production of specific metabolites from growth in biochemical substrates are interpreted as described in the package insert for conventional tubed media.

INTENDED USE FOR THE PASCO MIC AND MIC/ID PANELS:
PASCO MIC AND MIC/ID PANELS are used for quantitatively measuring (with the exception of the Breakpoint/ID panel which provides qualitative measurement or category results) the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms.

SUMMARY/CONCLUSION OF SUBSTANTIAL EQUIVALENCE TESTING:
Using routine manufacturing processes, antimicrobial agents were diluted in Cation Adjusted Mueller Hinton Broth to concentrations required for the Phenotypic Confirmatory Test (described in the NCCLS document M100-S11, Table 2A). For test purposes, additional concentrations other than those described in the M100-Sll were also included. Data presented here include the following antimicrobial concentrations- Cefotaxime (64-0.015 mcg/ml) and Ceftazidime (128-0.03 mcg/ml) with and without Clavulanic Acid (4 mcg/ml) for the ESBL Confirmatory Test.

Testing included a total of 30 challenge strains and 83 clinical isolates (78 ESBL-positive and 35 ESBL-negative) of *Klebsiella pneumoniae, K. oxytoca* and *E.coli* of various origin. Seventy four of these strains were genotypically characterized as ESBL producers or non-ESBL producers and 39 strains were phenotypically characterized. Reproducibility testing of 48 ESBL-positive and 35 ESBL-negative clinical strains was performed internally at Pasco and two external sites. Additional testing of 30 ESBL-positive challenge strains was performed at a third external site.

The percent correlation for the Pasco ESBL Confirmatory Test was !00% for detection of the ESBL-producing test strains and 99% for detection of the ESBL negative strains, with an overall percent correlation of 99.6%.

A minimum of 25 QC results for the two NCCLS recommended QC strains, which included *E. coli* ATCC 25922 (ESBL-negative) and *K. pneumoniae* ATCC 700603 (ESBL-positive) were acceptable for each of the four sites.

The results of the reproducibility, challenge strain testing and QC performance testing supports Substantial Equivalence as outlined as applicable in the FDA draft document "Review Critiera for Assessment of Antimicrobial Susceptibility Devices" Draft, March 8. 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 4 2001

Ms. Linda K. Dillon
Technical Manager
12750 West 42nd Ave.
Wheat Ridge, CO 80033

Re: 510(k) Number: K011116
Trade/Device Name: PASCO MIC and MIC/ID Panels
Inclusion of ESBL Confirmatory Test
Regulation Number: 866.1640
Regulatory Class: II
Product Code: LTT
Dated: January 31, 2001
Received: February 21, 2001

Dear Ms. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011116

Device Name: PASCO MIC and MIC/ID Panels **Inclusion of ESBL Confirmatory Test**

Indications For Use:

Pasco MIC and MIC/ID panels are used for quantitatively measuring (with the exception of the Breakpoint/ID panel which provides qualitative measurement of category results) the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms. The Pasco ESBL Confirmatory Test Panel is used for the confirmation of Extended Spectrum *B*-lactamase (ESBL) production of *Klebsiella pneumoniae, K. oxytoca* and *E. coli* isolates that have been found to be suspicious for ESBL production by the ESBL Screen Test.

This 510(k) notification is for use of the following antimicrobial concentrations included in the Pasco ESBL Confirmatory Test Panel for the purpose of confirming ESBL-producing strains.

Cefotaxime	64 - 0.25 mcg/ml
Cefotaxime/Clavulanic Acid	64/4 - 0.25/4 mcg/ml
Ceftazidime	128 - 0.25 mcg/ml
Ceftazidime/Clavulanic Acid	128/4 - 0.25/4 mcg/ml

For all *Klebsiella pneumoniae, K. oxytoca* and *E. coli* isolates confirmed as ESBL-producing strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins and aztreonam.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubow

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011116

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)